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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 09/698,479 | 10/30/2000 | Vance Bergeron | 8439.004.USCP00 | 6625 |
| 77213 | 7590 | 01/15/2009 | EXAMINER | |
| Novak Druce + Quigg, LLP 1300 Eye Street, NW, Suite 1000 Suite 1000, West Tower Washington, DC 20005 | | | CHEUNG, WILLIAM K | |
| ART UNIT | PAPER NUMBER | | | |
| | | 1796 | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 09/698,479 | Applicant(s) BERGERON ET AL. |
| | Examiner WILLIAM K. CHEUNG | Art Unit 1796 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

Status

- 1) Responsive to communication(s) filed on 11 November 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,6-15,17-41 and 43-48 is/are pending in the application.
- 4a) Of the above claim(s) 14,15 and 19-41 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,6-13,17,18 and 43-48 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. 09/318,941.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 110708
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

1. In view of the amendment filed November 11, 2008, claims 5, 16, 42 have been cancelled. Claims 1-4, 6-15, 17-41, 43-48 are pending. Claims 14-15, 19-41 are drawn to non-elected subject matter. Claims 1-4, 6-13, 17, 18, 43-48 are examined with merit.

2. In view of the amendment filed November 11, 2008, the rejection of Claims 1-4, 6-13, 17, 18, 43-48 under 35 U.S.C. 112, first paragraph, is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1-4, 6-13, 17, 18, 43-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (line 3), claim 2 (line 3), claim 3 (line 2), claim 4 (line 3-7), claim 6 (line 4, and the last three lines of claim 6), claim 7 (last two lines), claim 44 (line 2), the recitations "about" are considered indefinite because they fail to properly set the metes and bound of the claim.

Applicant's arguments filed November 11, 2008 have been fully considered but they are not persuasive. Applicants argue that the recitation "about" is acceptable in view of MPEP 2173.05(b). However, the examiner disagrees because applicants fail to

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recognize that applicants' specification fails to provide any indication as to what range of specific activity is covered by the term "about". *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991). Applicants must recognize that without defining what range of specific activity is covered by the term "about", the recitations "about" in the claims as written fail to set the metes and bound of the claims.

A. "About"

** In determining the range encompassed by the term "about", one must consider the context of the term as it is used in the specification and claims of the application. *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1326, 81 USPQ2d 1427, 1432 (Fed. Cir. 2007). In- *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. However, the court held that claims reciting "at least about" were invalid for indefiniteness where there was close prior art and there was nothing in the specification, prosecution history, or the prior art to provide any indication as to what range of specific activity is covered by the term "about." *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).

Claims 6 (the last line), the recitation "molecular weight" is considered indefinite because it is unclear on what type of molecular weight is being referenced to, a weight average molecular weight, a number average molecular weight, or a molecular weight that is determined by viscosity measurement method, or other techniques.

Claim 7 (last 2 lines), the recitation "the molecular weight of the polymer is in the range of about 10,000 to about 300,000 daltons as determined via conventional gel permeation chromatography" is considered indefinite because it is unclear as to what type of molecular weight that the claims are referring to. Applicants must recognize that depending on the computation method used, different type of molecular weights (such

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as number average molecular weight and weight average molecular weight) can be calculated. Therefore, specifying the use of GPC for measuring molecular weight is inadequate for overcoming the 112 rejection set forth.

Claim 44 (line 2-3), the recitation "an molecular weight of about 35,000 to about 300,000 daltons as determined via conventional gel permeation chromatography" is considered indefinite because it is unclear as to what type of molecular weight that the claims are referring to. Applicants must recognize that depending on the computation method used, different type of molecular weights (such as number average molecular weight and weight average molecular weight) can be calculated. Therefore, specifying the use of GPC for measuring molecular weight is inadequate for overcoming the 112 rejection set forth.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William K Cheung whose telephone number is (571) 272-1097. The examiner can normally be reached on Monday-Friday 9:00AM to 2:00PM; 4:00PM to 8:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David WU can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/William K Cheung/
Primary Examiner, Art Unit 1796

William K. Cheung, Ph. D.
Primary Examiner
January 12, 2009

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